SECTION 5 – 510(k) SUMMARY

K063482

[Submitted pursuant to 21 CFR 807.92(a). All data included in this document are accurate and complete to the best of DSC's knowledge.]

DEC 14 2006

1. Submitter Information

Date:	November 3, 2006
Submitter:	Direx Systems Corporation 437 Turnpike Street Canton MA 02021
Telephone:	(339) 502-6013
Fax:	(339) 502-6018
Contact Person	Larisa Gershtein QA Manager
Contact Person e-mail address:	lgershtein@direxusa.com

2. Device

Trade/Proprietary Name:	AccuSoft-XL v. 4.04, will also be marketed as *CrossPlan*
Classification Name:	System, Planning, Radiation Therapy Treatment
Regulation Number:	21 CFR 892.5050
Regulatory Class:	Class II (special controls)
Product code:	90 MUJ
Panel:	Radiology Devices

3. Predicate Devices

Direx Systems Corp	AccuSoft-XL v. 4.01	(K062032)
ADAC Laboratories Inc,	Pinnacle^3 RTP v. 6.6	(K032724)

4. Intended Use:

CrossPlan / AccuSoft-XL v. 4.04 is to be used for the computation, display, evaluation and output of radiation dose estimations to be submitted for independent clinical review and judgment prior to use in radiation therapy.

5. Device Description

CrossPlan / AccuSoft-XL v. 4.04 is an upgraded version of the Company's proprietary AccuSoft-XL. *CrossPlan / AccuSoft-XL v. 4.04* is a radiation treatment planning system (RTPS), consisting of a collection of software modules that execute algorithms to produce estimates of beam radiation dose distribution in body tissues. It includes the image, delineation and beam planning techniques.

CrossPlan / AccuSoft-XL v. 4.04 is designed to operate with Cones, Blocks and Wedges, as well as with a Micro-Multi-Leaf Collimator (MMLC), such that the shape of the radiation beam conforms to the irregular shape of the lesion. The ability to shape the radiation beam enables maximization of the radiation dose to the lesion, while minimizing the radiation dose to the surrounding normal tissue and critical structures.

CrossPlan / AccuSoft-XL v. 4.04 is used for computation, display, evaluation, and output of dose estimations, including those for several modes of treatment, such as Conformal, Blocks and Wedges, Cones and Intensity Modulated Radiation Therapy (IMRT). There are several IMRT treatment modes: (1) Intensity Modulated Arc Therapy (IMAT) – in which an irradiating Linac rotates while leaves form a sequence of apertures (arcs), (2) Dynamic Intensity Modulated Radiation Therapy (DIMRT) – in which irradiating Linac is stationary while leaves form a sequence of apertures, as well as (3) Intensity Modulated Radiation Therapy (also called Step-and-Shoot), during which apertures are formed prior to irradiation

As an option, some of the data can be imported via DICOM server that will include information of RT objects (RT Plan, RT Structure Set, RT Images) and CT Images.

CrossPlan / AccuSoft-XL v. 4.04 is able to combine two registered images to create a fusion image. This is often used to combine two images acquired differently but from a single source to enhance the display of various materials or tissues.

6. Performance Testing

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

However, *CrossPlan / AccuSoft-XL v. 4.04* complies with the following voluntary standards:

- Guidance for FDA Reviewers and Industry – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; May 11, 2005.
- IEC 60601-1-4 - Consol. Ed. 1.1 Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems (1996) + A1 (1999).
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices; September 9, 1999.

7. Substantial Equivalence

CrossPlan / AccuSoft-XL v. 4.04 is a modification of its predicate AccuSoft-XL (K062032).

CrossPlan / AccuSoft-XL v. 4.04 differences relative to its predicate devices do not raise additional safety or effectiveness issue as evidenced by performance validation.

Based on the descriptive information and the performance testing we believe that *CrossPlan / AccuSoft-XL v. 4.04* is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Larisa Gershtein
QA Manager
DIREX System Corporation
437 Turnpike Street
CANTON MA 02021

DEC 14 2006

Re: K063482
Trade/Device Name: Accusoft-XL v.4.04 (also be marketed under the name CrossPlan)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: November 15, 2006
Received: November 17, 2006

Dear Ms. Gershtein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DiREX
SYSTEMS CORP.

Section 4: Indications for Use Statement

Indications for Use STATEMENT

510(k) Number (if known): K063482

Device Name:

Accusoft-XL v.4.04 (also be marketed under the name CrossPlan)

Indications for Use:

Accusoft-XL v.4.04 / CrossPlan is to be used for the computation, display, evaluation and output of radiation dose estimations to be submitted for independent clinical review and judgment prior to use in radiation therapy.

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR § 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063482

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